



100 188.062102

#4

DECLARATION FOR PATENT APPLICATION

As the below-named inventors, we hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am an original, first inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled METHODS OF DIAGNOSING LIVER FIBROSIS, the specification of which

\_\_\_ is attached hereto as Attorney Docket No. \_\_\_\_).

X was filed on February 28, 2002, as Application Serial No. 10/087,188 (Attorney Docket No. P-PM 4978).

and was amended on (or amended through) \_\_\_\_\_.  
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified application, including the claims, as amended by any amendment(s) referred to above.

I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to myself to be material to patentability as defined in Title 37, Code of Federal Regulations, Sec. 1.56.

Under Sec. 1.56, information is material to patentability when it is not cumulative to information already of

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record or being made of record in the application, and (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or (2) It refutes, or is inconsistent with, a position the applicant takes in: (a) Opposing an argument of unpatentability relied on by the U.S. Patent and Trademark Office, or (b) Asserting an argument of patentability.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of first inventor:

Inventor's signature:

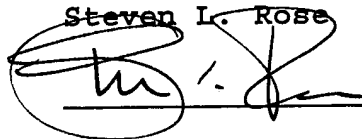
Date:

Residence:

Citizenship:

Mailing Address:

Steven L. Rose



April 23, 2002

Escondido, California USA

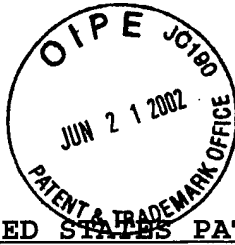
USA

3207 Avenida Reposo  
Escondido, CA 92029 USA

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Full name of second inventor: Esther H. Oh  
Inventor's signature: Esther H. Oh  
Date: June 13, 2002  
Residence: San Diego, California USA  
Citizenship: USA  
Mailing Address: 11462 Cypress Woods Drive  
San Diego, CA 92131 USA

Full name of third inventor: Michael J. Walsh  
Inventor's signature: Michael J. Walsh  
Date: June 17, 2002  
Residence: San Diego, California USA  
Citizenship: USA  
Mailing Address: 3621 Overpark Road  
San Diego, CA 92130 USA



PATENT

Our Docket: P-PM 4978

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: )  
 Rose et al. )  
 )  
 Serial No.: 10/087,188 )  
 )  
 Filed: February 28, 2002 )  
 )  
 For: METHODS OF DIAGNOSING )  
 LIVER FIBROSIS )  
 )

Commissioner for Patents  
 Washington, D.C. 20231

Sir:

**SMALL ENTITY STATEMENT**

The U.S. Patent and Trademark (USPTO) permits parties that establish status as a Small Entity to pay certain reduced fees (all citations to 37 C.F.R. § 1.27 except as noted). To be entitled to Small Entity Status, a party must be at least one of the following:

**(1) Individual person:**

An individual person, including an inventor and persons to whom an inventor has transferred some rights in the invention. § 1.27(a)(1).

**(2) Small business concern:**

A business concern whose number of employees, including affiliates, does not exceed 500 persons. § 1.27(a)(2) (incorporating 13 C.F.R. § 121.802).

"Business concern" means individual proprietorship, partnership, limited liability company, corporation, joint venture, association, trust or cooperative. If the concern is a joint venture, participation by foreign business

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entities may not be more than 49%. 13 C.F.R.  
§ 121.105.

The "number of employees" is the average number of employees, including the employees of its domestic and foreign affiliates, based on numbers of employees for each of the pay periods for the preceding completed 12 calendar months.

"Employees" includes all individuals employed on a full-time, part-time, temporary, or other basis. Part-time and temporary employees are counted the same as full-time employees. If a concern has not been in business for 12 months, use the average number of employees for each of the pay periods it has been in business. 13 C.F.R. § 121.106.

Concerns are "affiliates" of each other when one concern directly or indirectly controls or has the power to control the other, or when a third party or parties controls or has the power to control both concerns. 13 C.F.R. § 121.103(a).

### **(3) Nonprofit organization:**

A university or other institution of higher education located in any country. § 1.27(a)(3)(ii)(A).

An organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from taxation under section 501(a). Also included are such organizations located in a foreign country that would qualify if it were located in this country. § 1.27(a)(3)(ii)(B), (D).

A nonprofit scientific or educational organization qualified under a nonprofit organization statute of a U.S. state. Also included are such organizations located in a foreign country that would qualify if it were located in this country. § 1.27(a)(3)(ii)(C), (D).

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Please note that a license to the Government resulting from a rights determination under Executive Order 10096 does not constitute a license that would prohibit claiming Small Entity Status. Similarly, for small business concerns and nonprofit organizations, a license to a Federal agency resulting from a funding agreement with that agency under 35 U.S.C. § 202(c)(4) is not a license that would prohibit claiming Small Entity Status. § 1.27(a)(4).

I hereby assert that I am empowered to sign on behalf of the party identified below ("Party"). Persons empowered to sign include an inventor him- or herself or an authorized officer of the assignee, where the assignee has at least an undivided part interest in the application or patent. § 1.27(c)(2).

I have made a determination of the Party's entitlement to Small Entity Status, including a determination that all parties holding rights in the invention qualify for Small Entity Status. § 1.27(f).

I hereby assert that the Party has not assigned, granted, conveyed or licensed--and is under no obligation under contract or law to do so--any rights in the invention to any other party that would not qualify as a Small Entity. If the rights in the invention held by the Party are not exclusive, each party having rights in the invention is listed below:

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Separate assertions of Small Entity Status should be obtained from each party having rights to the invention.

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I hereby assert that the Party is entitled to be accorded Small Entity Status by the USPTO for the application or patent identified above. § 1.27(c)(1).

I understand that Small Entity Status must be newly determined when the issue fee and each maintenance fee is due. If there is any change resulting in loss of entitlement to Small Entity Status, I acknowledge the duty to file a notification to the USPTO in this application or patent before or upon paying the fee. § 1.27(g).

I understand that Small Entity Status must be separately established in any related application, including continuation, divisional, continuation-in-part, continued prosecution application or reissue application. § 1.27(c)(4).

I understand that any attempt to establish Small Entity Status improperly, deceptively or fraudulently will be considered a fraud practiced on the USPTO and may result in abandonment of the application or jeopardize the validity and enforceability of any resulting patent. § 1.27(h).

6/5/02  
Date

RB Rich  
Name: Russell Richardson

Title: V.P. R&D

PROMETHEUS LABORATORIES, INC.  
5739 Pacific Center Boulevard  
San Diego, California 92121-4203



Power of Attorney for Patent  
Application by Assignee  
Attorney Docket No.: P-PM 4978  
Serial No.: 10/087,188

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Box Missing Parts, Commissioner for Patents, Washington, D.C. 20231, on June 17, 2002.

By Andrea L. Gashler  
Andrea L. Gashler, Reg. No. 41,029

June 17, 2002  
Date of Signature





#7

STATEMENT UNDER 37 C.F.R. § 3.73(b)

Title of Application: METHODS OF DIAGNOSING LIVER FIBROSIS  
Application Ser. No.: 10/087,188  
Filed: February 28, 2002  
Inventors: Rose et al.  
Attorney Docket No.: P-PM 4978

PROMETHEUS LABORATORIES, INC., a corporation, states that it is the assignee of the entire right, title and interest in the patent application identified above by virtue of an assignment from the inventors of the application. A copy of the executed assignment, submitted for recording, is attached hereto as documentary evidence of the chain of title to the assignee.

The undersigned is empowered to sign this statement on behalf of the assignee.

PROMETHEUS LABORATORIES, INC.

Date: 6/5/02

Signature: R. B. Rickerson

Name: Russell Rickerson

Title: V-P. R&D

ASSIGNMENT

COPY

This Assignment is made by Steven L. Rose of Escondido, California, Esther H. Oh of San Diego, California, and Michael J. Walsh of San Diego, California, Assignors, to PROMETHEUS LABORATORIES, INC., Assignee, having a place of business at 5739 Pacific Center Boulevard, San Diego, California, 92121-4203, USA.

WHEREAS, Assignors have invented a new and useful METHODS OF DIAGNOSING LIVER FIBROSIS, for which an application for United States Letters Patent was filed on February 28, 2002, in the United States Patent and Trademark Office, bearing Serial 10/087,188, and identified as Attorney Docket No: P-PM 4978; \_

WHEREAS, Assignors believe themselves to be the original inventors of the invention disclosed and claimed in said application for Letters Patent; and

WHEREAS, the parties desire to have a recordable instrument assigning the entire right, title and interest in and to said invention, said application and any Letters Patent that may be granted for said invention in the United States and throughout the world;

NOW, THEREFORE, in accordance with the obligations to assign the invention and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Assignors sell, assign, and transfer to Assignee, the entire right, title, and interest in and to said invention, said application, any applications entitled to benefit of priority to

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said application under Title 35, United States Code, Sections 120, 121 or 251, which include divisionals, continuations and reissues, and any Letters Patent that may be granted on said invention or these applications in the United States and throughout the world, including the right to file foreign applications directly in the name of the Assignee and to claim for any such foreign applications any priority rights to which such applications are entitled under international conventions, treaties, or otherwise.

Assignors agree that, upon request and without further compensation, but at no expense to Assignors, they and their legal representatives and assigns will do all lawful acts, including the execution of papers and the giving of testimony, that may be necessary or desirable for obtaining, sustaining, reissuing, or enforcing Letters Patent in the United States and throughout the world for said invention, and for perfecting, recording, or maintaining the title of Assignee, its successors and assigns, to said invention, said application, and any Letters Patent granted for said invention in the United States and throughout the world.

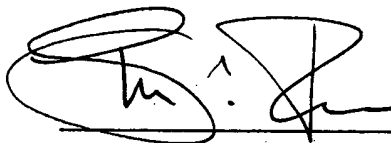
Assignors represent and warrant that they have not granted and will not grant to others any rights inconsistent with the rights granted herein.

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Assignors authorize and request that any United States or foreign Letters Patent granted for said invention, whether on said application or on any subsequently filed divisional, continuation or reissue application, be issued to Assignee, its successors and assigns, as the assignee of the entire interest in said invention.

IN WITNESS WHEREOF, Assignors have executed this Assignment on the date(s) provided below.

Assignor: Steven L. Rose

  
Signature

4/23/02  
Date

STATE OF California )  
COUNTY OF San Diego )

On 4-23-02, before me, Cecilia Huerta  
personally appeared Steven L. Rose,  
\_\_\_\_\_ personally known to me - OR - ☒ proved to me on the basis  
of satisfactory evidence to be the person~~(s)~~ whose name~~(s)~~ is are  
subscribed to the within instrument and acknowledged to me that  
he/she/they executed the same in his/her/their authorized  
capacity~~(ies)~~, and that by his/her/their signature~~(s)~~ on the  
instrument the person~~(s)~~, or the entity upon behalf of which the  
person~~(s)~~ acted, executed the instrument.

WITNESS by hand and official seal.

Cecilia Huerta  
(Signature of Notary)



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Serial No.: 10/087,188  
Filed: February 28, 2002  
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Assignor: Esther H. Oh

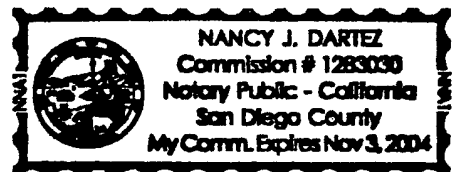
Esther H. Oh June 13, 2002  
Signature Date

STATE OF California )  
COUNTY OF San Diego )

on June 13, 2002, before me, Nancy J. Dartez, Notary Public  
personally appeared Esther H. Oh,  
\_\_\_\_\_ personally known to me - OR \_\_\_\_\_ proved to me on the basis  
of satisfactory evidence to be the person(s) whose name(s) is/are  
subscribed to the within instrument and acknowledged to me that  
he/she/they executed the same in his/her/their authorized  
capacity(ies), and that by his/her/their signature(s) on the  
instrument the person(s), or the entity upon behalf of which the  
person(s) acted, executed the instrument.

WITNESS by hand and official seal.

Nancy J. Dartez  
(Signature of Notary)



Inventors: Rose et al.  
Serial No.: 10/087,188  
Filed: February 28, 2002  
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Assignor: Michael J. Walsh

Michael J. Walsh June 11, 2002  
Signature Date

STATE OF California )  
COUNTY OF San Diego )

on June 11, 2002, before me, Nancy J. Dartez, Notary Public  
personally appeared Michael J. Walsh  
X personally known to me - OR - ~~proved to me on the basis~~  
~~of satisfactory evidence~~ to be the person(s) whose name(s) is/are  
subscribed to the within instrument and acknowledged to me that  
he/~~she/they~~ executed the same in his/~~her/their~~ authorized  
capacity(~~ies~~), and that by his/~~her/their~~ signature(s) on the  
instrument the person(s), or the entity upon behalf of which the  
person(s) acted, executed the instrument.

WITNESS by hand and official seal.

Nancy J. Dartez  
(Signature of Notary)

